RECEIVED AT DRUG SAFETY SURVEILLANCE
27-FEB-1998-0457

McNEIL CO
FORT

Individual Safety Report
3037714-4-00

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event: / Date of birth:	3. Sex	4. Weight
Case 2 In confidence	74 yrs	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (x) death (mo/day/yr) 5/1/93
- ( ) life-threatening
- (x) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event (mo/day/yr): 4/29/93

4. Date of this report (mo/day/yr): 02/11/98

5. Describe event or problem

Reports of 19 cases compiled by attorney & sent to FDA;Agency forwarded these reports to McNeil upon request to Docket No.77N-094W,Ref.94,Vol.6 of 7. Of the 19 cases, 11 were previously submitted to FDA by McNeil (Mfr.# 0158783A,0171537A, 0284020A,0325998A,0374114A,0495613A,0505064A,0505223A, 0505252A,0599479A,0673820A). Case document #2 of a 74yo female w/prior heavy ethyl alcohol hx was admitted to hosp on 4/29/93 w/2d hx of N/V & generalized ill feeling. Pt had been consuming a lot of analgesics including DARVOCET® and acetaminophen (up to 10-12 5gr tabs/day) (OVERDOSE) for pain. In hosp, pt noted to have elevated LFTs, metabolic acidosis & HEPATORENAL SYNDROME w/multiple organ failure. Pt died (DEATH) on 5/1/93. Autopsy final dx: massive central lobular hepatocellular necrosis (LIVER NECROSIS) c/w toxin induced hepatocellular damage, swelling & pallor of kidney w/acute tubular necrosis (KIDNEY TUBULAR NECROSIS), generalized JAUNDICE, moderate pulmonary edema (LUNG EDEMA), moderate abdominal ASCITES & ischemia of proximal small bowel.

6. Relevant tests/laboratory data, including dates

4/29/93: LDH=10,776 U/L, GOT=10,584 U/L, GPT=4308 U/L, GAMMA GT=476 U/L, CPK=374 U/L, BUN=30mg/dL, SCr.=4.4mg/dL, UA=10.8 mg/dL, WBC=22,300, Hct=38.2, PLT=220,000, PT=30.5, PTT=55.5, pH=6.95, PCO2=13, PO2=86, HCO3=3.1, (See Sect 87)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

hx of recent surgery on left toes, hypertension, past hx of low thyroid, significant sciatica & abnormal LFTs, gravida 5, para 4, AB 1; post-menopausal; drinks 1-2 cups of caffeine/day & ethyl alcohol use has been heavy in the past, but she reportedly has been off alcohol last 4-6 wks (Sect B6 cont'd): % saturation=92.9%, acetaminophen (See Sect C10)

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect product(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 unspecified acetaminophen product
   - #2 DARVOCET®
2. Dose, frequency & route used
   - #1 up to 10-12 5gr tabs/day
   - #2 unknown dose, q4h prn, po
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   - #1 unknown dates or duration
   - #2 unknown dates or duration
4. Diagnosis for use (indication)
   - #1 post-surgical pain
   - #2 post-surgical pain
5. Event abated after use stopped or dose reduced
   - #1 ( ) Yes ( ) No (X) N/A
   - #2 ( ) Yes ( ) No (X) N/A
6. Lot # (if known)
   - #1 Unknown
   - #2 unknown
7. Exp. date (if known)
   - #1 Unknown
   - #2 unknown
8. Event reappeared after reintroduction
   - #1 ( ) Yes ( ) No (X) N/A
   - #2 ( ) Yes ( ) No (X) N/A
9. NDC # - for product problems only (if known)
   - -
10. Concomitant medical products and therapy dates (exclude treatment of event)

PROCARDIA® XL (since 2/15/93) and DYAZIDE® (since 2/15/93) (Sect B7 cont'd): level=23ug/ml; hepatitis A & B serologies were negative; chest X-ray showed congestion and edema 4/30/93: lactate was high at 149mg/dL

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)
- ( ) foreign
- ( ) study
- ( ) literature
- ( ) consumer
- ( ) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- (x) other: attorney

4. Date received by manufacturer (mo/day/yr): 12/31/97

5. (A) NDA # 17-552
   IND #
   PLA #
   pre-1938 ( ) Yes
   OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE	HEPATORENAL SYN
DEATH	JAUNDICE
NECROSIS LIVER	NECRO KIDNEY TU
EDEMA LUNG	ASCITES

9. Mfr. report number: 0932272A

FEB 27 1998

E. Initial reporter

1. Name, address & phone #

[redacted]

2. Health professional? ( ) Yes (X) No

3. Occupation: attorney

4. Initial reporter also sent report to FDA: (X) Yes ( ) No ( ) Unk